

AMENDMENTS TO THE SPECIFICATION

Please amend specification paragraphs [0004], [0005] and [0044] - [0046] as follows, wherein underlining indicates additions and strikethroughs and double brackets indicate deletions.

[0004] In addition, the invention is directed to a device to produce pharmaceutical piston stoppers made substantially from rubber or a similar elastomer, which have a receiving cavity for connecting with a piston rod or a similar displacement transferring element and a piston section which, in the working position, faces the contents of a syringe or carpule cylinder and is enveloped in a cap-like manner by a fluorinated polymer film or a similar inert film. The piston section, which may have a conical shape and/or a substantially flat face, abuts on the outer circumference with its inert film against the syringe or carpule cylinder. The piston stopper has adjacent to this piston section an uncoated sealing section which, along with an entire edge region of the inert film, flatly abuts in the working position against the syringe or carpule cylinder. A forming tool forms the piston stopper from a layered arrangement comprising a non-vulcanized rubber sheet and a fluorinated polymer film or a similar inert film, wherein the forming tool has at least one first die plate and a second die plate interacting with the former, which can be displaced relative to one another into closed and open positions. A blanking device separates the piston stoppers from a layered arrangement flange laterally projecting beyond the piston stoppers and remaining in the region of the partition plane of the forming tool.

[0005] The invention is further directed to a pharmaceutical piston stopper, which has a base body made from rubber or a similar elastomer, a receiving cavity within the base body for connecting a piston rod or a similar displacement transferring element and a piston section proximate a first end of the base body enveloped by a fluorinated polymer film or similar inert film. The piston section, in the working position, faces the contents of a syringe or carpule cylinder and abuts with its inert film on the outer circumference against the syringe or carpule cylinder. The piston stopper has an uncoated sealing section proximate a second end of the base body and adjacent to this piston section, the uncoated sealing section abutting in the working

position against the syringe or carpule cylinder, and has at least one continuous sealing lip on its outer circumference.

[0044] As it can be particularly well seen in FIGS. 9 and 11, the piston stopper 2 has a single-piece base body 7' made from rubber or a similar elastomer, that is enveloped in a cap-like manner by a fluorinated polymer film or a similar inert film 9' on a cap-shaped section 8 of the piston which faces the contents of the syringe or carpule cylinder 1. The piston section 8 is preferably completely enclosed in or covered with the inert film 9'. A non-coated sealing section 10 of the piston stopper 2 is adjacent to this piston section 8. It can be seen in FIGS. 10 and 12 that on its outer circumference the piston stopper 2 abuts against the inside wall of the carpule cylinder 1 with both the edge region of the entire inert film 9' and the sealing section 10.

[0045] On its outer circumference the sealing section 10 has a first portion formed of a plurality of continuous sealing lips 11, that are spaced from one another by continuous recesses 12 situated between them on the outer circumference of the sealing section 10. Thus, the first portion has at least two continuous sealing lips 11 forming a seal on an outer circumference of the base body 7', in which the two lips are spaced-apart by a continuous recess 12. [[A]] The recess 12 is also provided between the inert film 9' and the sealing lip 11 adjacent to the inert film 9'. Between this recess 12 and the inert film 9' the sealing section 10 has on its outer surface a second portion or an annular continuous sealing zone 13, that has a generally flat side profile and adjoins directly the edge of the inert film 9'. The second portion or annular continuous sealing zone 13 is positioned between the first portion and the piston section 8. The uncoated sealing section 10 further includes a third portion having a frustoconical shape. The third portion connects to the first portion proximate the second end of the base body 7'. The sealing zone 13 is aligned with the surface of the edge region of the inert film 9' abutting against the inside wall of the syringe or carpule cylinder 1 or projects slightly radially beyond ~~this surface~~ the surface of the entire edge region of the inert film 9'. Specifically, an outermost circumferential edge of the continuous sealing zone 13 forms a plane with, is directly adjacent to and is in continuous abutting contact with the entire outermost circumferential edge of the inert film 9'. For purposes of this specification, "plane" is defined as a flat or level surface. In the

working position the piston stopper 2 abuts with the sealing zone 13 fully against the syringe or carpule cylinder 1. Due to this the recesses 12 are reliably sealed against the liquid pharmaceutical preparation situated in the cylindrical cavity 4, so that the preparation cannot interact there with the elastomer. Consequently, the sealing zone 13 prevents the penetration into the adjacent recess 12 of the pharmaceutical preparation between the inert film 9', with a poorer sealing than that of the non-coated elastomer, and the inside wall of the syringe or carpule cylinder 1. Moreover, the sealing zone 13 also seals the pharmaceutical preparation against the penetration of moisture, gases and/or germs. In addition, the cylindrical cavity 4 is sealed by the sealing lips 11 that are in a series with the sealing zone 13.

[0046] As can be seen from FIGS. 9 and 11, the receiving cavity 6 extends from the receiving orifice situated at that end region of the piston stopper 2 that is remote from the inert film 9' up into the piston section 8 and terminates there at a distance from the inert film 9'. Further, the receiving cavity 6 has a bottom section 6b having a first diameter and the receiving orifice has a second diameter. The second diameter is larger than the first diameter.